



# UNITED STATES PATENT AND TRADEMARK OFFICE

*Cur*

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/722,620

11/26/2003

Richard J. Melker

UF-246XCD1

7104

23557 7590 01/17/2008  
SALIWANCHIK LLOYD & SALIWANCHIK  
A PROFESSIONAL ASSOCIATION  
PO BOX 142950  
GAINESVILLE, FL 32614-2950

EXAMINER

TURK, NEIL N

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

01/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<b>Application No.</b> 10/722,620	<b>Applicant(s)</b> MELKER ET AL.	
	<b>Examiner</b> Neil Turk	<b>Art Unit</b> 1797	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 09 January 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: none.  
 Claim(s) objected to: none.  
 Claim(s) rejected: 1, 2, 4-27, 29 and 30.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE


8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_.

Continuation of 3. NOTE: The amendments to the claims would require further search and consideration as the claims now recite additional elements not previously acted upon on the merits.

Continuation of 11. does NOT place the application in condition for allowance because: of arguments of record. Further, with respect to claims 5, 17, and 23-26 Applicant's arguments are moot such that the claims have been amended and have thereby not previously been acted upon on the merits. Applicant's arguments with respect to the rejection of the claims under 35 USC 112, 2nd paragraph are maintained as previously discussed. Examiner further notes that Applicant cites that "depending upon the mode of administration the odorous marker can be detected following enzymatic breakdown. Examiner points out that the 112 rejection, in part, recites that such a mode of administration has not been recited in the claims. With respect to the claims rejected under 35 USC 102(e) over Katzman, Applicant argues that Katzman does not assess a patient's breath for odorous compounds. Examiner argues that Katzman discloses using flavorings in the compositions used for oral administration and such flavorings would act as odorous markers detectable in the exhaled breath for the qualitative assessment of an indication of compliance/non-compliance in taking the medicine. Examiner further asserts that Applicant has not established a specific chemical gas indicative of a particular odor, and thus any substance taken by the patient may be said to be "odorous" and thereby qualitatively detectable in the least. Examiner further asserts that the detection of the exhaled breath in Katzman (labels including flavorings, which are "odorous" and detectable, when the drug is orally administered) and the determination of the concentration of the metabolite is indicative of the drug being taken/not taken, given qualitative and/or quantitative concentration measurement of the metabolite. With respect to the claims rejected under 35 USC 102(b) over Forester, Applicant argues that Forester does not teach methods for monitoring patient compliance in taking medication. Examiner argues that Forester teaches a medication with an odorous marker, in which the steps of taking the medication and sampling the breath are implicitly recited as one would be able to detect exhaled breath from the living subject taking the cough drop. With regards to the claims rejected under 35 USC 103(a) over Forester in view of Payne and Kell, Applicant argues that the combination is improper. Examiner argues that no such deficiencies exist in Forester and that the disclosure of Kell was brought in for its recognizing the importance of monitoring patient compliance in taking medication, not for disclosure to urine analysis. Further, Payne discloses a known gas sensing semiconductor technology that can be used to show the presence or absence of the menthol (or flavor ingredient in Forester). The combination is maintained proper as previously discussed on the record. With respect to claim 22 rejected under 35 USC 103(a) over Forester in view of Payne and Ueda, Applicant argues that the combination is improper. Examiner asserts that no such deficiencies exist in Forester and Payne, and thereby the combination of Forester in view of Payne and Ueda is maintained as previously discussed on the record. With respect to claim 22 rejected under 35 USC 103(a) over Katzman in view of Payne and Ueda, Applicant argues that the combination is improper. Examiner asserts that no such deficiencies exist and thereby the combination is maintained proper as previously discussed on the record..

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700